CHANGE ONE THING

INTRODUCING THERANOVA FOR EXPANDED HEMODIALYSIS [HDx]

CHANGE EVERYTHING

DE NOVO GRANTED
NOW AVAILABLE
**THE PROBLEM**

Conventional/large middle-molecules are linked to chronic inflammation, cardiovascular disease (CVD), secondary immunodeficiency, erythropoietin resistance, symptom burden and other dialysis related comorbidities.\(^1\)\(^-\)\(^4\) Accumulation of these uremic toxins result in elevated concentrations in patients with Kidney Failure (KF), and may cause adverse biologic effects.\(^1\)

Conventional/large middle-molecules may contribute to disease burden in kidney failure patients.\(^1\)\(^,\)\(^2\)

Accumulation of conventional/large middle molecules may contribute to disease burden in kidney failure patients.\(^1\)\(^,\)\(^2\)

In a National Kidney Foundation (NKF) online survey, majority of patients (n=359) receiving in-center hemodialysis reported experiencing interdialytic symptoms:\(^9\)

\begin{itemize}
  \item 62% of patients feel fatigued/washed out
  \item 40% of patients report 4+ hours of recovery time
  \item 6% of patients skipped a dialysis session
\end{itemize}

These QoL symptoms were severe and correlated with longer recovery time following hemodialysis, as well as shortened and skipped hemodialysis sessions.\(^9\)
**THE SOLUTION**

The Theranova MCO membrane’s unique design includes a tight pore size distribution, with increased nominal pore size and pore density that delivers a **steep sieving curve** resulting in **higher permeability** for uremic toxins (up to 45,000 Da), while **selectively retaining** endotoxins/essential proteins and maintaining **stable albumin** levels.

The minimized diameter (180 microns) of the Theranova membrane **enhances internal filtration** expanding solute removal, creating a stable separation profile and **selectivity** throughout treatment.

**HDx ENABLED BY THERANOVa: ONE STEP CLOSER TO THE NATURAL KIDNEY**

<table>
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<tr>
<th>Classification of uremic solutes by molecular weight (Daltons)</th>
<th>Low Flux</th>
<th>High Flux</th>
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<td>Small Molecules &lt;500 Da</td>
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<td>Conventional Middle Molecules 500 Da - &lt;25 kDa</td>
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<td>Large Middle Molecules 25 kDa - 45 kDa</td>
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<td>Essential Proteins</td>
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</tbody>
</table>

- Urea (60 Da)  
- Phosphate (96 Da)  
- PTH (9,500 Da)  
- Beta microglobulin (12 kDa)  
- Cystatin C (13 kDa)  
- Myoglobin (17 kDa)  
- Kappa free-light-chains (23 kDa)  
- Complement factor D (24 kDa)  
- Interleukin-6 (25 kDa)  
- Alpha 1 microglobulin (33 kDa)  
- YKL-40 (40 kDa)  
- Lambda free-light-chains (45 kDa)  
- Albumin (67 kDa)

**THERANOVA 4 KEY DIFFERENTIATORS**
- Higher Permeability  
- Selectivity  
- Retention  
- Enhanced Internal Filtration

**Classification of uremic solutes by molecular weight (Daltons)**

- Small Molecules: <500 Da
- Conventional Middle Molecules: 500 Da - <25 kDa
- Large Middle Molecules: 25 kDa - 45 kDa
- Essential Proteins

**THE THERANOVA PAES/PVP ASYMMETRICAL AND POROUS MEMBRANE HAS THREE DISTINCT LAYERS**
- Support Structure
- Selective Layer
- Intermediate Layer

The selective layer is the most important layer in the function of the membrane including the permeability profile.


**PERFORMANCE CHARACTERISTICS OF VARIOUS BLOOD FILTRATION MEMBRANES**

- Low flux  
- High flux  
- Theranova  
- Glomerular membrane  
- Osmotrix molecular weight (g/mol)
**HDx ENABLED BY THERANOA: NOW IS THE TIME TO CHANGE EVERYTHING**

Conventional/large middle molecular (500-45,000 Da) uremic toxins have been linked to the development of inflammation, cardiovascular disease (CVD) and other dialysis related comorbidities.

CVD is associated with inflammation, atherosclerosis and calcification. ~50% of patients with kidney failure (KF) die from CVD.

Traditional high-flux membranes, have limited capability to remove conventional and large middle molecular uremic toxins (up to 45,000 Da).

**CHANGE ONE THING.**

The unique design of the Theranova membrane delivers superior removal of conventional/large middle molecules (up to 45,000 Da), compared to high-flux membranes, while selectively retaining essential proteins and maintaining stable albumin levels.

HDx therapy showed a significant reduction in hospital days and in-center medication usage, in a retrospective analysis (n=81).

A Randomized Control Trial (n=86) showed 43% reduction in all-cause hospitalizations. Improvement in certain inflammatory markers were observed in select patients (n=41).

**CHANGE EVERYTHING.**

Theranova, the next evolution in hemodialysis (HD) brings us a step closer to the natural kidney by expanding clearance of conventional/large middle molecules (up to 45,000 Da) linked to inflammation and CVD, compared to traditional HD.

HDx therapy may improve patient reported kidney disease Quality of Life (QoL) outcomes including symptom burden, restless leg syndrome (RLS) criteria uremic pruritus and dialysis recovery time.

**Simply change the dialyzer membrane to expand clearance and CHANGE EVERYTHING for your patients.**

For more details contact your Baxter representative or visit https://hemodialysis.baxter.com/HDx.
REFERENCES:
8. Aoki J, Ikari Y, Cardiovascular Disease in Patients with End-Stage Renal Disease on Hemodialysis, Ann Vasc Dis Vol 10, No 4; 2017; 327-337.

The Theranova Dialyzer is indicated for patients with chronic kidney failure who are prescribed intermittent hemodialysis. It provides an expanded solute removal profile with increased removal of various middle and large molecules [up to 45 kDa] that may play a pathologic role in the uremic clinical syndrome. The Theranova Dialyzer is not intended for hemofiltration or hemodiafiltration therapy. The total extracorporeal blood volume for the Theranova Dialyzer and the set should represent less than 10% of the patient’s blood volume.

For Single Use Only

Rx Only. For safe and proper use of these devices refer to the Instructions for Use.

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